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CITATIONS

510856—43——1

In the Supreme Court of the United States

OCTOBER TERM, 1942

No. 717

THE UNITED STATES OF AMERICA, PETITIONER

v.

JOSEPH H. DOTTERWEICH

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SECOND CIRCUIT

The Solicitor General, on behalf of the United States, prays that a writ of certiorari issue to review the judgment of the United States Circuit Court of Appeals for the Second Circuit, entered December 3, 1942 (R. 282), setting aside a conviction for violations of the Federal Food, Drug, and Cosmetic Act of 1938.

OPINION BELOW

The opinion of the Circuit Court of Appeals (R. 278–282) is reported in 131 F. (2d) 509.

JURISDICTION

The judgment of the Circuit Court of Appeals was entered on December 3, 1942, and petition for

rehearing was denied on January 4, 1943 (R. 287). The jurisdiction of this Court is invoked under Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925.

QUESTION PRESENTED

Whether the manager of a corporation, as well as the corporation itself, may be prosecuted under the Federal Food, Drug, and Cosmetic Act of 1938 for the introduction of misbranded and adulterated articles into interstate commerce.

STATUTE INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040 (21 U. S. C., secs. 321–381), are printed in Appendix A, *infra*, pp. 12–14.

STATEMENT

On April 29 and August 15, 1940, informations were filed in the District Court for the Western District of New York, naming as defendants Buffalo Pharmacal Company, Inc., a corporation, and respondent Joseph H. Dotterweich, alleging violations of Section 301 (a) of the Federal Food, Drug, and Cosmetic Act through introduction of misbranded and adulterated drugs into interstate commerce, and delivery of such goods for such introduction (R. 3–11). The two informations were consolidated for trial, and three counts were submitted to the jury (R. 20, 21, 23). The jury

disagreed as to the corporation but convicted respondent Dotterweich on all three counts (R. 23). On October 27, 1941, he was sentenced to a five-hundred dollar fine on each count, but payment was suspended as to all but one count, and he was placed on sixty days' probation (R. 24, 270–271.)

The pertinent counts of the information charged the introduction and delivery for introduction in interstate commerce of (1) a bottle of misbranded cascara compound, on or about October 2, 1939; (2) a bottle of adulterated digitalis tablets, on or about January 9, 1940; and (3) a bottle of misbranded digitalis tablets, on or about January 9, 1940.

The evidence of misbranding in Count I was that the bottle bore a label reading, "1,000 tablets, cascara compound . . . (Hinkle)", followed by a list of ingredients, one of which was strychnine sulphate, but that at the time of shipment of the drug this formula was obsolete, since the then current revision of the official National Formulary, the statutory standard, Section 201 (j), Section 501 (b), omitted strychnine sulphate from the Hinkle formula (R. 16–17, 63–64). The evidence of misbranding and adulteration of the bottle of digitalis tablets under Counts II and III was that its label represented that each tablet possessed a potency of 1 U. S. P. unit of digitalis, although in fact the tablets were of less than one-half the pur-

ported potency, in violation of Sections 501 (c) and 502 (a) (R. 34, 81).[1]

The corporation was not itself a manufacturer of drugs, but a "jobber," purchasing its drugs from manufacturers, and had sold the drugs in question in interstate commerce after repackaging them under its own label (R. 27–28, 46, 197; 12, 16–17, 186–187). The individual defendant, respondent Dotterweich, was the corporation's general manager (R. 47, 58, 223). He had not himself packed or shipped the drugs, but was in general charge of the corporation's operations, the packaging and shipping having been carried out in accordance with his general instructions (R. 223–225). The court instructed the jury that his guilt required a finding that he was "responsible" for the shipments, that is, that they were made "under his supervision" "as General Manager" (R. 257).

The court below, while rejecting other contentions of the respondent, reversed the conviction on the ground that the criminal provisions of the Act were not aimed at employees but solely at nominal principals.[2] In reversing and remanding for new trial, the court directed that there be submitted to the jury the issue whether the appellant operated

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[1] The court below held that the findings of misbranding as to the first count, and of adulteration and misbranding as to the second and third counts, were supported by the evidence (R. 279).

[2] The phrase is used here to avoid confusion with the definition of principal in the Criminal Code, *infra*, p. 8, n. 5, which we deem applicable.

the corporation as his "alter ego" or agent. Judge Swan, who wrote the opinion, dissented on this issue of statutory construction.

SPECIFICATION OF ERRORS TO BE URGED

The Circuit Court of Appeals erred:

1. In construing the criminal provisions of the Federal Food, Drug, and Cosmetic Act of 1938 as not applicable to a responsible corporate officer such as respondent.

2. In reversing the judgment of conviction.

REASONS FOR GRANTING THE WRIT

The court below recognized that the criminal provisions of Section 303 (a) of the Act apply to "any person" who violates the prohibitions of the Act, and that criminal liability for the introduction of misbranded or adulterated goods into interstate commerce, which is prohibited by Section 301 (a), does not turn on want of good faith. Indeed, bad faith under the Act operates to increase the severity of the punishment. Section 303 (b). The majority below were influenced by their construction and oblique application of the immunity provision in Section 303 (c) (2), which provides that no "person" shall be subject to liability for violation of Section 301 (a) if he establishes a guaranty from the person "from whom he received in good faith the article." Construing this provision to confer immunity only on the "receiver" of the guaranty, and deeming the corporation to be the

receiver, the majority concluded that only the corporation could be liable in the present case.

In so holding, the court has rendered a decision of major importance in the enforcement of the Act, and one which overturns an administrative and judicial construction of long standing.

1. Since July 1, 1939, the earliest effective date of any of the provisions of the 1938 Act,[3] the Food and Drug Administration has initiated approximately 1,000 criminal cases. In the calendar year ended December 31, 1942, there were more than four hundred such cases. About one-half of these (208) involved corporate defendants, and in approximately 30 percent (61) one or more officers and employees of a corporation were joined as defendants. It has been the policy of the Food and Drug Administration, as a matter of administrative discretion, to avoid prosecution of mere underlings acting under instructions. The administration has held itself precluded from prosecuting even responsible officers and employees if the corporation holds a guaranty. The instant case serves as illustration. There is no suggestion of a guaranty here. The workmen who performed the actual operations of bottling, labeling and shipping were not named as defendants. Enforcement practice has recognized the fact that the statute, since

[3] Some of the provisions of the statute did not become effective at once, Section 902 (a); see also Act of June 23, 1939, c. 242, 53 Stat. 852, Section 1.

it imposes criminal liability for acts dangerous to the public even when committed without intent to harm, has as its aim the inculcation of an attitude of vigilant care on the part of the industries affected.[4] Accordingly, the individual defendants named in criminal prosecutions have tended to be persons such as respondent Dotterweich, persons with policy-making and discretionary functions quite apart from whether or not they control the whole enterprise, since it is those persons who have the power to initiate precautionary measures to avoid violation of the Act.

While the seizure provisions of Section 304 are unaffected by the instant decision, since they operate against the goods themselves and not against "persons," recourse to seizure is inadequate to remove adulterated or misbranded goods from the market without enforcement by an impracticably large investigative staff. Ordinarily, and particularly in the case of large corporations, the persons penalized by seizures or by the assessment of fines against the corporation are the stockholders, who may not even be aware of the penalty. Unless the individuals who actually carry on the business can be named as defendants, these persons gain immunity by reason of the corporate form, for the monetary loss through seizure or through fine imposed upon the corporation often operates merely as a

[4] See *United States* v. *Balint*, 258 U. S. 250, 252.

license fee to carry on the business in an illegal manner. It is the combined effect of the criminal, injunction, and seizure methods which gives the statute its present effectiveness in protecting the public from articles dangerous to health. Enforcement has therefore frequently proceeded directly against managerial personnel, taking the view that the prospect of jail sentence in a criminal case or in a contempt proceeding for violation of an injunction decree is the most effective deterrent.

2. The existing administrative practice, contemplating enforcement against responsible agents, officers, and employees who are above the level of mere hired hands, is a continuation of over thirty years' enforcement policy under the predecessor Act of 1906. Prosecutions of individuals have never been restricted to those who dominate the enterprise but have included persons with varying but substantial degrees of discretionary responsibility. The suggestion that criminal liability under the 1906 Act was restricted to nominal principals, individual or corporate, was repeatedly rejected by the courts in the early years of operation under that Act, and apparently never since raised. *United States* v. *Mayfield*, 177 Fed. 765 (N. D. Ala.); *United States* v. *Buffalo Cold Storage Co.*, 179 Fed. 865 (W. D. N. Y.); *United States* v. *Kellett* (D. Utah), reported in White and Gates.

Decisions of Courts in Cases under the Federal Food and Drugs Act (1934), pp. 711, 713.[5]

The 1906 Act likewise contained a guaranty provision in which there was implicit the very issue which the court below considered. Section 9, 34 Stat. 771, exempted a dealer from prosecution "when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, *from whom he purchases* such articles * * *." [Italics supplied.]. Thus under that Act, too, an argument was possible that the privilege of acquiring the guaranty immunity was restricted literally to those who purchase, i. e., to the principals, and that hence liability was also restricted to principals. Such an argument never found acceptance.

The practice of not prosecuting even responsible officials if the corporation holds a guaranty has

[5] Section 12 of the Act of June 30, 1906, c. 3915, 34 Stat. 768, 772, provided that "the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person." The Act antedated the general provision in the Criminal Code defining principals (Act of Mar. 4, 1909, c. 321, sec. 332, 35 Stat. 1152, 18 U. S. C., sec. 550): "Whoever directly commits any act constituting an offense defined in any law of the United States, or aids, abets, counsels, commands, induces, or procures its commission, is a principal."

been regarded by the Food and Drug Administration not as an exercise of discretion but as a conformance to statutory requirement. In the *Mayfield* case, *supra*, the court made clear that only because the corporation could not establish a guaranty were the officers subject to prosecution under the Act of 1906. See also *Turner* v. *State*, 171 Tenn. 36, 100 S. W. (2d) 236. In short, the guaranty has been treated as one running with the goods, for the purpose of allowing relaxation of vigilance where another person, in a position to exercise all necessary vigilance, is willing to assert that he has done so, for that person has thereby subjected himself under Section 301 (h) to prosecution should his guaranty be factually false.[6]

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[6] The construction by the court below of the guaranty provision in Section 303 (c) (2) leads to anomalous results. The next subsection, 303 (c) (3), relating to adulteration by use of uncertified coal-tar color, likewise contains a guaranty provision protecting "any person," but it does not mention the matter of "receiving" the articles. It is hardly to be supposed that Congress intended the scope of this guaranty and of criminal liabilty to be broader than under Section 303 (c) (2). The introduction of new drugs without certification is a violation of Section 301, as is the offense charged in the instant case; and Section 303 (c) (2) is likewise the relevant immunity provision. Under the lower court's construction, a manager could claim immunity under a guaranty in the case of coal-tar colors, and so presumably could be prosecuted in the absence of a guaranty, but not so in the case of new drugs, which might themselves be coal-tar products. This anomaly is avoided by treating the statute, in accordance with the administrative construction, as protecting any person who handles the goods on behalf of his principal.

CONCLUSION

3. Thirty-one state statutes contain provisions comparable to those in the instant case.[1] The decision below is thus likely to have an importance beyond its technical confines.

For the foregoing reasons it is respectfully submitted that this petition for a writ of certiorari should be granted.

CHARLES FAHY,
Solicitor General.

FEBRUARY 1943.

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[1] The state statutes are listed in Appendix B, *infra*, pp. 15–17. Under these statutes, there is likewise criminal liability for unintentional violation, and employees are not exempted by the mere existence of guaranty provisions. See: *Turner* v. *State*, 171 Tenn. 36, 100 S. W. (2d) 236; *People* v. *Schwartz*, 28 Cal. App. 775, 70 Pac. (2d) 1017; see also *Commonwealth* v. *Lutz*, 137 Pa. Sup. 449, 9 At. (2d) 481.

APPENDIX A

The Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, in pertinent part provides as follows:

SEC. 201. For the purposes of this Act—

* * * * * * *

(e) The term "person" includes individual, partnership, corporation, and association. (21 U. S. C. 321 (e).)

* * * * * * *

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

* * * * * * *

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false. (21 U. S. C. 331 (a) (h).)

* * * * * * *

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on con-

viction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, * * * (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Secretary under this Act if such person establishes a guaranty or undertaking

signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act. (21 U. S. C. 333.)

APPENDIX B

The Food and Drug Laws of the following States contain coverage and guaranty provisions which are substantially the same as those of the Federal Food and Drugs Act of 1906 and the Federal Food, Drug, and Cosmetic Act of 1938:

1. Alabama—Code of Alabama, 1940. Title 2, Sections 1 and 331.
2. Arizona—Code Annotated, 1939. Sec. 68–410, Sec. 68–412.
3. Arkansas—Part 1 of Ch. 70 of Pope's Digest, as amended by Act 10.190, Reg. Sess. of 1939. Sec. 6008, Sec. 6015.
4. California—Ch. 3 of Div. XXI of Health and Safety Code, added by Ch. 731, Laws of 1939; amended by ch. 1042, 1147, 1149, Laws of 1941. Sec. 26511, Sec. 26520.
5. Colorado—Statutes Annotated, 1935. Ch. 69, Sections 2, 9, 11.
6. Connecticut—Sec. 886e–919e of Ch. 135b of 1939 Supp. to General Statutes. Ch. 364, Laws of 1939 as amended by House Bill 2693, effective 1941, Sec. 3 (e), Sec. 6 (c).
7. Florida—Ch. 19656 (No. 661), Laws of 1939, Sec. 2 (b), Sec. 5 (b).
8. Georgia—Code Annotated, Sec. 42–108, Sec. 42–115, Sec. 42–9901.
9. Idaho—Code Annotated, 1932, Sec. 36–302, Sec. 36–311, Sec. 36–313.

10. Indiana—Burns Indiana Statutes Annotated, Sec. 35-1230 (e), Sec. 35-1233 (e).
11. Kansas—General Statutes Annotated, Sec. 65-602, Sec. 65-609, Sec. 65-610.
12. Kentucky—Revised Statutes, 1942, Sec. 217.060, Sec. 217.160, Sec. 217.990.
13. Louisiana—Act No. 142, Acts of 1936, amended by Act No. 185, Acts of 1942. Sec. 2 (e), Sec. 20 (d).
14. Maryland—Flack's Annotated Code, 1939, Art. 43, Sec. 189 and Sec. 193.
15. Massachusetts—Annotated Laws, Ch. 94, Sec. 191 and Sec. 193.
16. Michigan—Statutes Annotated, Title 14, Sec. 14.787 and Sec. 14.781.
17. Missouri—Statutes Annotated, Art. 2, Sec. 13027, Sec. 13028, Sec. 13029.
18. Montana—Revised Code, 1935. Ch. 237, Sec. 2578 and Sec. 2588.
19. Nebraska—Compiled Statutes, 1929, Sec. 81-908, Sec. 81-910, Sec. 81-911.
20. New Jersey—Statutes Annotated, Sec. 24:5-2, Sec. 24:1-3, Sec. 24:17-1.
21. New York—McKinney's Consolidated Laws, Art. 17, Bk. 2B, Sec. 198.2, Sec. 214.
22. North Carolina—S. Bill No. 232, Reg. Sess. 1939, Sec. 2 (b), Sec. 5 (b).
23. Oklahoma—Oklahoma Statutes, 1941, Title 63, Sec. 182 and Sec. 260.
24. Pennsylvania—Compiled Statutes (Purdon's), 1936, Title 31, Sec. 2 and Sec. 5.
25. Rhode Island—General Laws, 1938, Ch. 269, Ch. 1 and Ch. 7.
26. South Carolina—Code, 1942, Sec. 5128-27 (1) and (5).
27. South Dakota—Code, 1939, Sec. 22.0404, Sec. 22.0407, Sec. 22.9905.

28. Tennessee—Ch. 120, S. 568, 1941, Sec. 2 (b) and Sec. 5 (b).
29. Virginia—S. Bill 310, Reg. Sess. 1940, Sec. 2 (b) and Sec. 5 (b).
30. Washington—Pierce's Code, 1929, Sec. 2535 and Sec. 2539.
31. Wyoming—Revised Statutes 1931, Supp. 1940, Sec. 45–117, Sec. 45–118.

U. S. GOVERNMENT PRINTING OFFICE: 1943